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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,538	02/08/2002	Kevin B. Morton	NEOMTRX.004CP1	3962
20995	7590	08/11/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			FOREMAN, JONATHAN M	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3736	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,538

Applicant(s)

MORTON ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/29/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-42 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 30 is objected to because of the following informalities: Claim 30 depends on a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 – 4, 8, 15, 16, 21, 23 – 26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,733,319 to Neilson et al.

In regards to claims 1 – 4, 8, 15, 16, 21, 23 – 26 and 30, Neilson et al. discloses Applicant's claimed invention including a control unit (102); a patient interface unit (28); a control line (96A, 94A) extending between the control unit and the patient interface unit; and a closed recirculation flow path containing heat exchange media (Col. 5, lines 39 – 58), extending along the control line and providing communication between a first component (110) carried by the control unit and a second component (28) carried by the patient interface unit. The first component comprises a compressible reservoir removably carried by the control unit (Col. 6, lines 40 – 44). The flow path comprises a movable wall and a compressible tube (Col. 11, lines 22 – 28). The control unit includes a pump that causes fluid circulation through the flow path (Col. 11, lines 22 – 37).

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4. Claims 1 – 3, 5, 8, 13 – 18, 21, 23 - 27, 30 and 35 - 40 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,620,189 to Machold et al.

In regards to claims 1 – 3, 5, 8, 13 – 18, 21, 23 - 27, 30 and 35 – 40, Machold et al. discloses Applicant's claimed invention including a control unit (50); a patient interface unit (52); a control line (62) extending between the control unit and the patient interface unit (Col. 11, lines 40 – 42); and a closed recirculation flow path containing heat exchange media (Col. 12, line 4), extending along the control line and providing communication between a first component (54) carried by the control unit and a second component (76) carried by the patient interface unit. The first component comprises a compressible reservoir (Col. 25, lines 47 – 53) removably carried by the control unit (Col. 12, lines 24 – 28). The second component includes an inflatable bladder (Col. 12, lines 3 – 4). The flow path comprises a movable wall. The control unit comprises a heat source (Col. 11, lines 42 – 43). The first component is in thermal communication with the heat source (Col. 12, lines 42 – 47). The control unit comprises a pump (68) that causes fluid circulation through the flow path.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 7, 9 – 12, 28, 29 and 31 – 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,620,189 to Machold et al. in view of U.S. Patent No. 5,054,500 to Littleford, deceased et al.

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In regards to claims 6, 7, 9 – 12, 28, 29 and 31 – 34, Machold et al. discloses the second component comprising an inflatable bladder, but fails to disclose the size of the inflatable bladder and the bladder comprising at least 3, 4 or 6 inflatable lobes. Littleford, deceased et al. discloses an inflatable bladder having 4 inflatable lobes (Figure 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflatable bladder as disclosed by Machold et al. to include 4 inflatable lobes as taught by Littleford, deceased et al. to prevent the inflatable bladder from completely blocking the blood vessel and thereby restricting blood flow through the vessel to allow the catheter to remain for longer periods of time (Col. 5, lines 10 – 15). Duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to duplicate the inflatable lobes as taught by Littleford, deceased et al. in order to have at least 6 inflatable lobes if so desired. Additionally, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). It would have been obvious to one having ordinary skill in the art to modify the inflatable lobes to be any size as desired depending upon where in the body the catheter is to be placed.

7. Claims 19, 20, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,620,189 to Machold et al. in view of U.S. Patent No. 5,776,081 to Kreder.

In regards to claims 19, 20, 41 and 42, Machold et al. discloses a disposable patient interface unit (Col. 23, lines 24 – 27), but fails to disclose a disposable patient interface carried by the patient interface unit. However, Kreder discloses a disposable patient interface unit or a disposable flexible polymeric membrane carried by the patient interface unit to contact the patient (Col. 4, lines 18 – 22). It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to modify the patient interface unit as disclosed by Machold et al. to include a disposable flexible polymeric membrane as taught by Kreder in order to reuse the patient interface unit.

Allowable Subject Matter

8. Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF

August 9, 2004



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700